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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,336	09/12/2003	William J. Wechter	LOMACEN.015C5	8054
20995	7590	09/11/2006	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			RAMACHANDRAN, UMAMAHESWARI	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1617	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,336

Applicant(s)

WECHTER, WILLIAM J.

Examiner

Umamaheswari Ramachandran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/31/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's claim to priority to the following applications, 10/372,510, filed February 21, 2003, which is a continuation of U.S. Patent Application No. 10/134,140, filed April 26, 2002, now U.S. Patent No. 6,555,575, which is a continuation of U.S. Patent Application No. 09/814,330, filed March 21, 2001, now U.S. Patent No. 6,410,589, which is a continuation of U.S. Patent Application No. 09/461,645, filed December 14, 1999, now Patent No. 6,242,479, which is a continuation of U.S. Patent Application No. 09/215,608, filed December 17, 1998, now Patent No. 6,048,891 is acknowledged. The applicant is **granted priority only to September 12 2003** as the filing date as 'cerebral ischemia' is not disclosed anywhere in the specification or in the claims before this application was filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The specification describes the use of gamma-tocopherol and its metabolite LLU- α (gamma-CEHC) to treat a number of conditions: high blood pressure, thromboembolic disease, atherosclerosis, cardiovascular disease, cancer, natriuretic disease, the formation of neuropathological lesions and a reduced immune system response (Specification, p4 lines 1-3) and also to treat and prevent cardiovascular

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diseases such as ischemia, angina, edematous conditions, LDL-oxidation, adhesion of monocytes to endothelial cells, foam-cell formation, fatty-streak development, platelet adherence, platelet aggregation, smooth muscle cell proliferation, and reperfusion injury, treat and prevent cancers such as lung cancer, prostate cancer, breast cancer, colon cancer (Specification, p4 lines 12-17). Also the specification (p4 lines 21-26) describes the methods of treating and preventing natriuretic diseases such as hypertension, high blood pressure, ischemia, angina pectoris, congestive heart failure, cirrhosis of liver, nephritic syndrome, ineffective renal perfusion, or ineffective glomerular filtration and neurological diseases including hyperflexia, ophthalmoplegia, and axonal dystrophy. While, the specification describes the use of gamma-tocopherol for treating a variety of diseases, it does not describe a method for treating and/or ameliorating a symptom of neuronal damage associated with a cerebral ischemic condition in a mammalian subject by administering an effective amount of a non-alpha tocopherol enriched tocopherol composition. The specification provides examples for the isolation of natriuretic compound, bioassays for biological activity, synthesis of hydroxyl chromans and chroman esters, treatment and prevention of high blood pressure, thromboembolic disease, atherosclerosis, cancer, neuropathological lesions, reduction of platelet binding to adhesive proteins, reduction in the formation of free radicals, and modulation of immune system response. However, the specification does not provide adequate description and there are no specific examples to provide support to the claims. The claim(s) contains subject matter, which was not described in the

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specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support to the subject matter 'cerebral ischemic condition' that is claimed in claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-19 are rejected under 35 U.S.C. 102(a) as being anticipated over Miller et al. (US 2002/0143049).

Miller et al. teaches a method of treatment and/or ameliorating the symptoms of cerebral ischemia by administering non-alpha tocopherol enriched tocopherol composition, and by said administering, reducing neuronal damage related to said cerebral ischemic condition which addresses claim 1 (see claim 1). Claim 2, the non-alpha tocopherol in the composition being gamma tocopherol and its compositions (claims 7-10,13) are addressed in the reference (see claims 2, 15-18, 22). The reference teaches the gamma tocopherol metabolite in claims 3, 8 thereby addressing the claims 3 and 4 in the application. Claims 5 and 6 in the invention are addressed in claims 9 and 10 of the reference. The reference further teaches that gamma tocopherol enriched composition comprising 50-100% gamma tocopherol (col. 3 lines 3-18) which

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addresses claims 11 and 12. Claim 14 is addressed by the reference, which teaches that the gamma tocopherol metabolite enriched composition comprises of 5-95% of gamma tocopherol metabolite (col. 3 p53-69, col. 4 p70-73). Claims 15-18 are addressed by the reference (see claims 51-54). The reference also teaches the composition of non-alpha tocopherol for treating and/or ameliorating cerebral ischemic condition comprising gamma tocopherol in a range of 1-50 mg/kg body weight of said mammalian subject (claim 56) thus addressing claim 19.

Conclusion

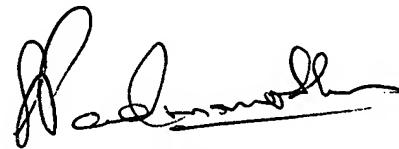
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER